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| EXAMINER | |
|---|---|
| WORLEY, CATHY KINGDON | |
| ART UNIT | PAPER NUMBER |
| 1638 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/595,610 | AMARAL REMER ET AL. | |
| | Examiner | Art Unit | |
| | CATHY K. WORLEY | 1638 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *4 and 22-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2009* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Restriction/Election*

1. In response to the communication received on Sept. 1, 2010, from Laurence P. Colton, the election without traverse of group I, claims 2 and 3, is acknowledged. Claims 1-30 are pending in the instant application. Claims 4 and 22-30 are withdrawn for being directed to non-elected inventions, but claim 4 is subject to rejoinder if a linking claim is found to be allowable, and claims 22-30 are subject to rejoinder if a product claim is found to be allowable (see guidance regarding rejoinder of process claims on pages 5-6 of the restriction requirement mailed on July 2, 2010). Claims 2 and 3 along with linking claims, claims 1 and 5-21 are examined in this Office Action.

### *Priority*

2. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country. A certified copy of the Brazilian Patent Application: BR PI0305197-8; filed on Nov. 13, 2003, has been received, however, priority to this application was not claimed in the Oath/Declaration, and there was no ADS submitted claiming priority to this Brazilian application. Also, the first sentence of the specification does not include

any reference to the parent PCT application or to the foreign Brazilian Application. For this reason, priority is only extended to Nov. 12, 2004; the filing date of the PCT Application from which this National Stage Entry depends.

***Oath/Declaration***

3. Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in Brazil on Nov. 13, 2003. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

***Information Disclosure Statement***

4. The Information Disclosure Statement (IDS) filed on Oct. 14, 2009, has been considered. Three of the Foreign Patent Documents that were submitted had only abstracts, therefore, the Examiner indicated "abstract only" for those particular documents. The Examiner relied on the foreign document from Robert et al (see rejection under 35 USC 102 (b), below, and therefore, the Examiner considered this document in its entirety.

## *Drawings*

5. The Drawings submitted on July 1, 2009, have additional pages after Figure 9 that include the sequences from the sequence listing. The Applicant should delete all pages after Figure 9, because these extra pages are not actually Figures and they do not include any label indicating that they are Figures (ie. Figure 10, Figure 11, etc.). The Applicant is advised to provide REPLACEMENT SHEETS that end after Figure 9, along with a statement that the extra pages are being deleted. Please make sure that each sheet is labeled as REPLACEMENT SHEET.

## *Specification*

6. The specification is objected to because it does not include a Brief Description of the Drawings. Please see, below, for guidance regarding the content of the specification:

Content of Specification:

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated

briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). **A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.**

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences

disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

7. The specification is also objected to because there are two sequences on page 36 in lines 24-26; and these sequences do not have identifiers. Applicant is advised to add these two sequences to their sequence listing and amend the specification to include the identifiers in parentheses next to the sequences on page 36. A new sequence listing must be submitted. The new sequences in the sequence listing must be identical to the sequences disclosed in the originally filed specification, and applicant is cautioned to avoid any new matter.

8. The title of the invention is not descriptive of the invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: - - PHARMACEUTICAL PRODUCT COMPRISING TRANSGENIC POLLEN EXPRESSING HETEROLOGOUS POLYPEPTIDES - - .

## *Claim Objections*

9. Claims 2, 3, and 5-21 are objected to because of the following informalities:

- Each of these claims contains an unnecessary comma. Applicant is advised to delete commas between “product” and “according" in claims 2, 3, 5-21.
- In addition, each of claims 6-12 include limitations that are essentially intended use limitations. The intended use of a product is not given weight in searching for prior art, unless the intended use limits the form or structure of the actual product. Therefore, recitations of “useful as”, “destined for”, or “results from” do not provide meaningful limitations. The Applicant is advised that the claims would be much more clear if the identity of the heterologous polypeptides is recited as a limitation in these claims or the identity of the formulation to be used for a particular type of administration is recited as a limitation in these claims. New Matter must be avoided.
- Claim 5 is specifically objected to because it appears to be a Markush-type claim, but it does not utilize proper Markush format. Applicant is advised that proper Markush language is "selected from the group consisting of:" followed by a list of choices separated by commas, and ending with "and" before the last item of the list.
- Claim 6 is specifically objected to because there is a typographical error. Applicant is advised to replace "eucaryotes" with - - eukaryotes - - .

- Claim 9 is objected to because it is grammatically incorrect due to the recitation of "the said". Applicant is advised to delete either "the" or "said".

Appropriate correction is requested.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims include the recitation "said immunotherapy is destined for" which is confusing and not grammatically correct. It is unclear how an immunotherapy can be "destined" for anything. It appears to be part of the intended use of the products, but it is unclear how the recited destiny affects the form, composition, or structure of the claimed products. The Applicant is advised to amend the claims to include limitations to the composition, form, or structure of the products.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3 and 5-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Robert et al (WO 99/49063; published on Sept. 30, 1999).

The claims are directed to a pharmaceutical product comprising at least part of tissues or cells of the male vegetal reproductive system containing heterologous polypeptides.

Robert et al teach the display of peptides or proteins on the surface of a pollen grain for protein production and antigen delivery (see pages 33-36). They teach that recombinant proteins and therapeutics may be expressed in transgenic plants and packaged on intact pollen grains with little process or purification (see page 35, lines 17-19). This pollen is a part of the male vegetal reproduction system and it is a part of an anther. They teach that any protein or peptide now used for the production of vaccines could be utilized this way, and they specifically name canine parvovirus coat protein (see page 35 lines 26-28 and page 34 line 26) which is a eukaryotic antigen and can be used for vaccination of a vertebrate. They also mention tritrpticin, leptin, avidin, interleukin (which can be used for treating allergies and autoimmune diseases), and interferon (which can be used for treating cancer) (see page 34, lines 5-6).

Robert et al specifically teach that the pollen expressing the peptide of interest can be administered orally or nasally to stimulate the mucosal immune

system (see page 35, lines 10-11). They teach that it could be administered intradermally, intramuscularly, intraperitoneally, intravenously, subcutaneously, and nasally (see page 35, lines 25-26), furthermore, the route for administration is an intended use rather than a limitation that changes the form or composition of the pharmaceutical product, therefore, it is not given weight against the prior art. Because the limitations in claims 17-21 are intended use limitations that do not require any change in the actually product, they do not have patentable weight. For example, the pollen grains that are displaying an antigen for use as a vaccine could be also used for an *in vitro* immunoreaction as claimed in claims 17-21.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/
Primary Examiner, Art Unit 1638